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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,074	09/25/2003	Kenneth W. Dobie	AMGN0001-101 (A-829A)	8427
35140	7590	06/07/2006	EXAMINER CHONG, KIMBERLY	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			ART UNIT 1635	

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/671,074	Applicant(s) DOBIE ET AL.	
	Examiner Kimberly Chong	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15, 19-29 and 42-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14, 19-29 and 48-51 is/are allowed.
- 6) ☒ Claim(s) 15, 42-47, 52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/16/06</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment</u> . |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 03/16/2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 01/25/2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 01/25/2006, claims 14-15, 19-29 and newly added claims 42-53 are pending in the application. Applicant has canceled claims 1-13.

All previous rejections under 35 USC § 102 or 35 USC § 103 for claims 1-13 and 19-29 are moot in view of the cancelled claims and amended claims.

Allowable Subject Matter

The indicated allowability of claim 15 is withdrawn in view of the new art rejections. Rejections based on the new art rejection(s) follow.

Claims 14, 19-29 and 48-51 are allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 recites the limitation "wherein each internucleoside linkage" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 53 recites the limitation "wherein each cytosine" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102 or 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 is rejected under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) as being anticipated by or obvious over Bentwich et al. (US 2006/0003322).

The instant claims are drawn to a compound 8 to 80 nucleobases in length targeted to a nucleic acid encoding forkhead box O1A wherein the compound is at least 70% complementary to said nucleic acid molecule and wherein the compound inhibits expression of said nucleic acid molecule and wherein the compound comprises at least 8 consecutive nucleobases of SEQ ID NO. 172.

Bentwich et al. teach an oligonucleotide (see attached sequence alignment SEQ ID NO. 155128, Result 1995 in database rnpbn), 22 nucleobases in length, targeted to a nucleic acid encoding a human forkhead box O1A wherein the compound is 90.9% complementary to the nucleic acid encoding a human forkhead box O1A. Thus, the nucleic acid sequence taught by Bentwich et al. meets the structural limitation of claim 15 of the instant application. See, for example, MPEP 2112, which states “[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. “There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.” *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Therefore, the instant claims are anticipated or obvious over Bentwich et al.

Claims 15 is rejected under 35 U.S.C. 102(e) or 35 U.S.C. 103(a) as being anticipated by or obvious over Zhou et al. (US 2005/0026164).

The instant claims are drawn to a compound 8 to 80 nucleobases in length targeted to a nucleic acid encoding forkhead box O1A wherein the compound is at least 70% complementary to said nucleic acid molecule and wherein the compound inhibits expression of said nucleic acid molecule and wherein the compound comprises at least 8 consecutive nucleobases of SEQ ID NO. 172.

Zhou et al. teach an oligonucleotide (see attached sequence alignment SEQ ID NO. 643422, Result 27 in database rnpbm), 15 nucleobases in length, targeted to a nucleic acid encoding a human forkhead box O1A wherein the compound is 100% complementary to the nucleic acid encoding a human forkhead box O1A. Thus, the nucleic acid sequence taught by Zhou et al. meets the structural limitation of claim 15 of the instant application. See, for example, MPEP 2112, which states “[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. “There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.” *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims

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claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Therefore, the instant claims are anticipated or obvious over Zhou et al.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Bentwich et al. (US 20060003322).

The instant claims are drawn to a compound 15 to 30 nucleobases in length comprising at least 8 consecutive nucleobases of SEQ ID No. 172 wherein the

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compound is at least 70%, 80%, 90% or 95% homologous to a nucleic acid molecule encoding forkhead box O1A.

Bentwich et al. teach a compound 22 nucleotides in length comprising 20 nucleotides of SEQ ID NO. 172 (see attached sequence alignment SEQ ID NO. 155128, Result 1995 in database rnpbn) wherein the compound is 90.9% complementary to a nucleic acid molecule encoding forkhead box O1A.

Thus, Bentwich et al. anticipates claims 42-47 of the instant application.

Claims 42-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhou et al. (US 2005/0026164).

The instant claims are drawn to a compound 15 to 30 nucleobases in length comprising at least 8 consecutive nucleobases of SEQ ID No. 172 wherein the compound is at least 70%, 80%, 90% or 95% homologous to a nucleic acid molecule encoding forkhead box O1A.

Zhou et al. teach a compound 25 nucleotides in length comprising 15 nucleotides of SEQ ID NO. 172 (see attached sequence alignment SEQ ID NO. 643422, Result 27 in database rnpbm) wherein the compound is 100% complementary to a nucleic acid molecule encoding forkhead box O1A.

Thus, Zhou et al. anticipates claims 42-46 of the instant application.

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Conclusion

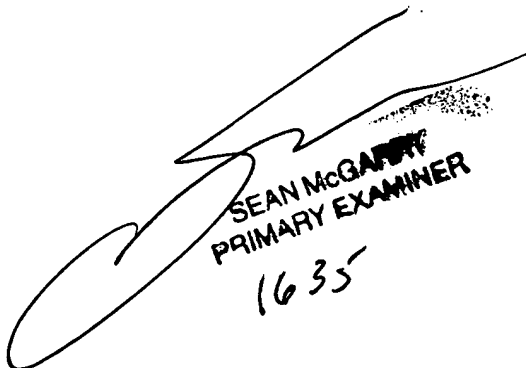
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached at 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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Kimberly Chong
Examiner
Art Unit 1635



SEAN MCGARVEY
PRIMARY EXAMINER
1635

Run on: January 12, 2006, 09:43:16 ; Search time 468 Seconds
(without alignments)
3.677 Million cell

updates/sec

Title: US-10-671-074-4
Perfect score: 5723
Sequence: 1 gcagccgccacattcaacag.....ctattaaatacttgagttaa
5723

Scoring table: IDENTITY_NUC
Gapop 10.0 , Gapext 0.5

Searched: 7335 seqs, 150361 residues

Total number of hits satisfying chosen parameters: 14670

Minimum DB seq length: 8
Maximum DB seq length: 80

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 11487 summaries

Database : fetch4rnpbn.seq:*

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score greater than or equal to the score of the result being
printed,
and is derived by analysis of the total score distribution.

RESULT 1995

US-10-310-914A-155128/c
; Sequence 155128, Application US/10310914A
; Publication No. US20060003322A1
; GENERAL INFORMATION:
; APPLICANT: Bentwich, Isaac
; APPLICANT: Shiler, Kvuzat
; TITLE OF INVENTION: Bioinformatically detectable group of novel
regulatory genes and
; TITLE OF INVENTION: uses thereof
; FILE REFERENCE: 06087.0200.CPUS01
; CURRENT APPLICATION NUMBER: US/10/310,914A
; CURRENT FILING DATE: 2002-12-06
; NUMBER OF SEQ ID NOS: 1388402
; SOFTWARE: PatentIn version 3.3
; SEQ ID NO 155128
; LENGTH: 22
; TYPE: RNA
; ORGANISM: Human

US-10-310-914A-155128

Query Match 0.3%; Score 18.8; DB 1; Length 22;
Best Local Similarity 90.9%; Pred. No. 2.1e+03;
Matches 20; Conservative 0; Mismatches 2; Indels 0;
Gaps 0;

Qy 2713 TTGTGTGTGTTTTTGGTTTTTC 2734
|||| |||||
Db 22 TTGTTTGTGTTTTTGGTTGTTTC 1